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Music during interventional radiological procedures, effect on sedation, pain and anxiety: a randomised controlled trial

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Objective: To assess the effects of playing patient-selected music during interventional procedures on (1) the doses of sedation and analgesia and (2) anxiety levels.
Methods: Patients undergoing interventional radiological procedures were randomised to either the intervention (music) or the control (no music) group. Patients in the intervention group had music of their choice played via headphones during the procedure. The primary outcomes were reductions in the doses of drugs for sedation (midazolam) and analgesia (fentanyl). Anxiety levels were assessed both before and after the procedure using the validated State Anxiety Inventory. Mean pulse rate and average of mean blood pressures were also recorded before and during the procedures as surrogate indicators of anxiety levels.
Results: 100 patients were randomised in a 1:1 ratio. There were 58 males and 42 females, with a mean age of 58 years. Sedation was required in 21 (42%) patients in the music group compared with 30 (60%) patients in the control group (p=0.046). The mean [standard deviation (SD)] midazolam dose was 2.1 mg (2.3 mg) in the control group and 1.3 mg (2.2 mg) in the music group (p=0.027). The mean (SD) fentanyl dose was 29 mg (40 mg) in the control group and 18 mg (34 mg) in the music group (p=0.055). There was no significant effect of music on the change from baseline in anxiety levels (p=0.74), pulse rate (p=0.56) or blood pressure (p=0.34).
Conclusion: Sedation requirements are significantly reduced by playing self-selected music to the patient during interventional radiology procedures. By lowering sedation during interventional radiology, music makes the procedure safer. It also contributes favourably to the overall patient experience.

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An increasing number of radiological interventional (IR) procedures, both vascular and non-vascular, are being performed worldwide. Most IR procedures are performed under local anaesthesia with a varying need for conscious sedation [1]. Conscious sedation carries small risks that are occasionally life threatening, *e.g.* respiratory depression [2]. Therefore the dose and need for conscious sedation should be minimised without compromising patient comfort during the procedure.

Patients experience varying levels of anxiety before and during these procedures [3]. Factors known to reduce anxiety and analgesic requirements during procedures include adequate pre-operative information, with a pre-operative visit, and familiarity with the personnel involved. A meta-analysis of randomised trials concluded that music reduces anxiety and analgesic requirements during endoscopy [4].

Playing music during the procedure is common practice in some IR radiology departments. This may not be directly for the patient's benefit and they are often not consulted on the choice of music or offered headphones. One might expect a more patient-focused approach to reduce patient anxiety and pain. To our knowledge, the effect of music during IR procedures has not been investigated. The aim of this randomised study was to assess the effect of per-operative patient-selected music during IR procedures on:

1. dose of sedation and analgesic drugs
2. anxiety levels.

Methods and materials

Approval for the study was obtained from the local ethics committee.

Patient selection

All adult patients undergoing an IR procedure in our centre were considered for the study. The following exclusion criteria were applied:

- patients undergoing emergency procedures
- procedures under general anaesthesia
- unable to consent
- hearing difficulty.

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If eligible, patient information leaflets were enclosed along with the appointment letters. To participate in the study, patients were requested to bring a music compact disc (CD) of their choice.

Randomisation

Patients were randomised in blocks to either the study (music) group or the control (no music) group. Block size was randomly chosen to be four or six, with equal probability. This was a computer-generated randomisation process, with the sequencing concealed by sealed and consecutively numbered envelopes.

Consent

Eligibility was assessed and consent obtained by the IR radiologist performing the procedure. For elective inpatient procedures, the study was discussed with the patient and consent obtained on the ward at least 24 h before the procedure. For the more urgent inpatients, again study consent was obtained on the ward at least 24 h prior to the procedure. Patients who required more urgent procedures were not included, as per the exclusion criteria.

Patients undergoing outpatient IR radiology procedures are routinely seen in a radiology outpatient clinic in our practice. These patients, if eligible, were consented for the study at this clinic visit.

Before the procedure

On arrival in the IR radiology suite, patient and procedure identification was performed as per routine practice. The patient's consent and music CD were checked. If the patient's own music CD was unavailable, his/her choice of music was made available from the department's collection. If this was not possible, then the patient was excluded from the study. The IR procedure planned, patient demographics, any pre-existing medical conditions and any regular patient medications were all recorded. The patient also completed the State Anxiety Inventory (SAI), which is a validated questionnaire indicating anxiety state. The patient's baseline pulse rate and mean blood pressure values were also recorded as surrogate markers of anxiety state. Just prior to the procedure, the randomisation envelope was opened, the patient's group revealed and the patient informed of this.

During the procedure

During the IR procedure, headphones were applied to all patients. The study group had self-selected music played to them at a comfortable volume and the control group had no music played. Pulse rate and mean blood pressure were recorded at 10 min intervals throughout the procedure and averaged at the end. The duration of the procedure was also recorded. Patient sedation and analgesia were administered as required following the departmental protocol. The requirement and doses of both sedation (intravenous midazolam) and analgesia (intravenous fentanyl) were recorded.

After the procedure

The patient's pulse rate and mean blood pressure were recorded. If the patient was undergoing an inpatient procedure, this was performed on the ward, 24 h after the procedure. In day-case procedures, the recordings were performed just prior to discharge. At this time, patients completed the SAI questionnaire again and the score was recorded.

Statistical analysis

Intervention effects on continuous measures were tested using *t*-tests, where the assumption of normal errors appeared justified (SAI score), and using proportional odds logistic regression adjusted for the baseline SAI score otherwise (midazolam and fentanyl dosage). Intervention effects on the change from baseline in continuous measures (pulse rate and blood pressure) were investigated using baseline-adjusted linear regression models (analysis of covariance). Interactions between intervention effects on midazolam and fentanyl dosage and patient subgroups (by sex, age and duration of procedures) were investigated using proportional odds ordinal logistic regression. All analyses were performed in the R v. 2.10.0 statistical software [5].

Results

A total of 120 study invitations to eligible patients were made. 17 patients wanted music to be played during the procedure and refused consent for randomisation. A further three patients were excluded owing to lack of the patient's choice of music. This study therefore comprised 100 patients, with 50 patients in each group of comparable demography, morbidity and intended procedures. This is illustrated as a consort flow chart in Figure 1.

The overall and individual group baseline characteristics of these patients, including the type of procedure, are summarised in Table 1. Patients randomised to the music group had a significantly higher pulse rate at baseline than patients in the control group (77 *vs* 71 beats per min). No other baseline characteristic differed significantly between the study groups.

Sedation was required in 21 (42%) patients in the music group compared with 30 (60%) patients in the control group (p=0.046). Significantly lower doses of midazolam sedation were recorded in the music group, with a mean dose [standard deviation (SD)] of 1.3 mg (2.2 mg) compared with 2.1 mg (2.3 mg) in the control group (p=0.027).

Analgesia was administered to 18 (36%) patients in the music group compared with 26 (52%) patients in the control group (p=0.085). The dosage of fentanyl analgesia was also lower in the music group [mean dosage (SD) of 18 mg (34 mg) in the study group compared with

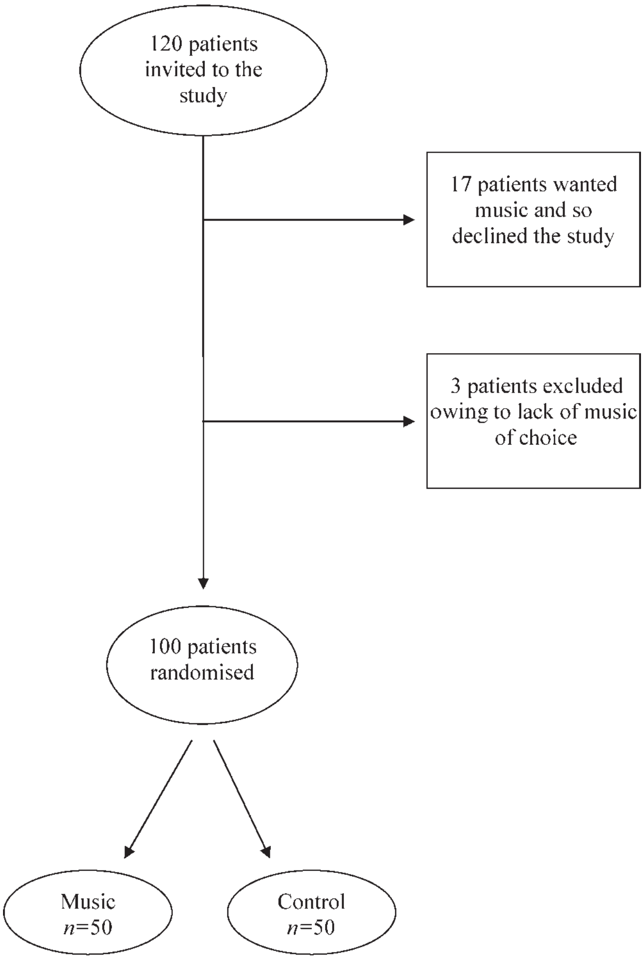

Figure 1. Consort flow chart.

29 mg (40 mg) for the control group], but not significantly (p=0.055). Table 2 summarises the sedation and analgesia requirements in both groups. The subset analysis (sex, age and duration of procedure) of the midazolam and fentanyl doses is summarised in Table 3.

The SAI scores of the patients in the two groups before and after the procedure are illustrated in Figure 2.

There was no significant difference between groups in the change from baseline in pulse rate or blood pressure (Figure 3).

Discussion

To our knowledge, this is the first randomised control study comparing the effects of music on sedation, analgesia and anxiety during radiological procedures

With the exception of pulse rate, the baseline characteristics, as well as other variables including the background morbidities and duration of procedures, were comparable between the two groups. As the baseline pulse rate was measured before the randomisation status was revealed, this difference must be a chance result.

Significantly fewer patients in the music group required any sedation than the controls (p=0.046). This is because patients undergoing some interventional procedures, such as varicocele embolisation or straightforward angioplasties, are not sedated as routine. The distributions of these cases are comparable between the two groups, so this should be an intervention (music) effect rather than a chance finding. The music group was also associated with a significantly lower dosage of midazolam sedation than the control group (p=0.027). A meta-analysis by Tam et al [6] exploring the effect of music on sedation during colonoscopy returned a similar decreased requirement for sedation in the music group. A possible explanation offered is that patients listening to familiar music are more relaxed and so require a lower sedation dose. Koch et al [7] suggested a relationship between auditory stimuli and stress response. The relative exclusion of ambient noise (auditory stimuli) contributes to the lower doses of sedation and analgesia required. The mode of action may be physiological or psychological, but playing music of the patient's choice during the IR procedure decreases the need for sedation and contributes favourably to patient experience.

There are a number of studies reporting positive effects of music on pain [7–9]. The mechanism is not fully understood. One hypothesis is that positive emotional valence contributes to music-induced analgesia. Another, as discussed above, involves the relationship between auditory stimuli and stress. Although in our study lower mean (18 *vs* 26 μg) and median (0 *vs* 20 μg) fentanyl doses were also recorded in the music group, this intervention effect marginally failed to reach statistical significance. Similarly, a non-significant intervention benefit was seen with respect to the numbers of patients requiring any analgesia.

It is difficult to assess patient anxiety states during IR procedures objectively. In this study, anxiety states were measured prior to and after the IR procedure using a

Table 1. Baseline characteristics of the study and control groups, with p-values for between-group differences from logistic regression (categorical variables) and t-tests (continuous variables)

Baseline characteristic		Total (n=100)	Control (n=50)	Music (n=50)	p-value
Sex	Male	58 (58%)	27 (54%)	31 (62%)	0.418
Age (years)	Mean (SD)	58 (16)	59 (15)	57 (16)	0.445
	Range	16–91	22–83	16–91	
Duration of procedure (min)	Mean (SD)	60 (24)	60 (22)	60 (26)	0.870
	Range	25–130	25–120	25–130	
Mean pre-procedure pulse rate	Mean (SD)	74 (11)	71 (8)	77 (13)	0.012
	Range	57–111	57–98	58–111	
Mean pre-procedure blood pressure (mmHg)	Mean (SD)	105 (16)	107 (16)	103 (17)	0.271
Type of procedure	Vascular	41 (41%)	21 (42%)	20 (40%)	0.895

SD, standard deviation.

Table 2. Patient outcomes, with tests of differences between intervention groups adjusted for baseline State Anxiety Inventory score. For categorical outcomes, *p*-values and odds ratios (95% CI) are estimated using logistic regression. For continuous outcomes, *p*-values are from Wald tests of odds ratios estimated from proportional odds logistic regression models

			Intervention (n_{MISSING}=0)			
Drug name	Parameters	Total	Control	Music	Odds ratio (95% CI)	*p*-value
Midazolam dose (mg)	*n* (%) >0 mg	51 (51%)	30 (60%)	21 (42%)	0.43 (0.19, 0.99)	0.046
	Median (IQR) [range]	1.5 (0.0, 4.0) [0–8]	2.0 (0.0, 4.0) [0–8]	0.0 (0.0, 2.0) [0–8]	–	0.027
Fentanyl dose (μg)	*n* (%) >0 μg	44 (44%)	26 (52%)	18 (36%)	0.49 (0.21, 1.11)	0.085
	Median (IQR) [range]	0 (0, 40) [0–160]	20 (0, 40) [0–160]	0 (0, 20) [0–140]	–	0.055

CI, confidence interval, IQR, interquartile range.

Table 3. Analgesia and sedation—mean dose requirements in the sex, age group and duration of procedure subsets. *p*-values for intervention effects and interactions are from Wald tests of proportional odds logistic regression models adjusted for baseline State Anxiety Inventory score

	Midazolam				Fentanyl			
Subset	Music (mg)	Control (mg)	*p*-value	Interaction *p*-value	Music (μg)	Control (μg)	*p*-value	Interaction *p*-value
Male	1.3	2.1	0.082	0.860	10	24	0.030	0.235
Female	1.9	2.6	0.176		31	36	0.681	
Age >60 years	1.1	1.8	0.067	0.856	8	24	0.039	0.342
Age <60 years	1.8	3.0	0.095		25	36	0.383	
Duration of precedure								
>60 min	2.0	2.9	0.083	0.670	27	34	0.195	0.911
<60 min	1.1	1.7	0.238		11	24	0.224	

simple and objective questionnaire—the SAI. This is based on Speilberger's SAI [10], which is a validated 20-item anxiety questionnaire. The scores range from 20 to 80, with higher scores suggesting higher anxiety levels. The patients in the study completed this independently without any help from any member of staff or their family. Patients in both groups returned higher pre-procedure than post-procedure SAI scores. This is intuitively expected with any surgical or IR procedure, as the patients are likely to be more anxious before the procedure than afterwards. In our study there were no significant differences between the music and the control groups.

Average pulse rate and average mean blood pressure were taken as surrogate markers of patient anxiety [10]. Whilst these are reliable indicators of anxiety, they are influenced by both the sedative as well as the analgesic [11]. The results demonstrate a higher mean pulse rate change and mean blood pressure change in the control group than in the music group (Figure 3). Whilst not statistically significant, this should be interpreted against the background of higher sedation and so physiological lowering of the parameters in the control group. Given this, the change of the mean pulse rate and mean blood pressure in the control group is likely to be higher. This supports a possible anxiolytic effect of music [12, 13].

This study has been performed in the setting of an IR radiology suite. However, the factors involved are generic to any invasive procedure performed under conscious sedation, be it within radiology such as ultrasound/CT-guided procedures or in other clinical areas such as minor surgeries and endoscopy [14]. The findings can be extrapolated.

Limitations of the study

This is a small, single-centre study. The small numbers limit the ability to draw meaningful conclusions from any of the subset analyses. Patients who did not bring their own music had to be offered a choice from the hospital collection, which was limited. The administration of conscious sedation was pragmatic and clinically guided. A more objective parameter, such as the bispectral index, was not used [15].

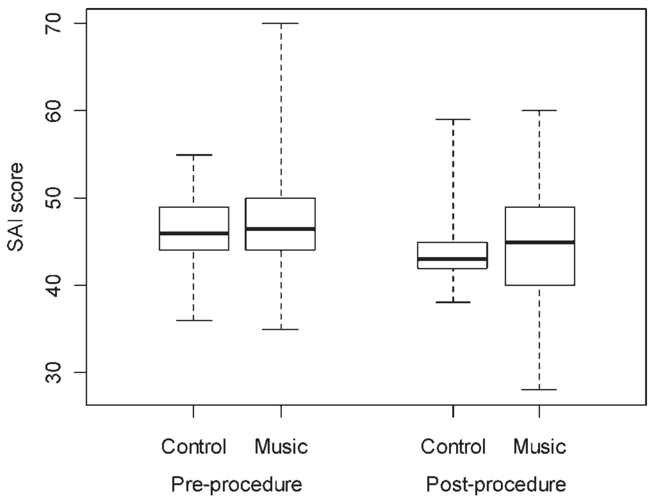

Figure 2. Box-and-whisker plot of the State Anxiety Inventory (SAI) scores in the two groups. The box encloses the first and third quartile with the median shown as a thick line, and the whiskers extend to the range.

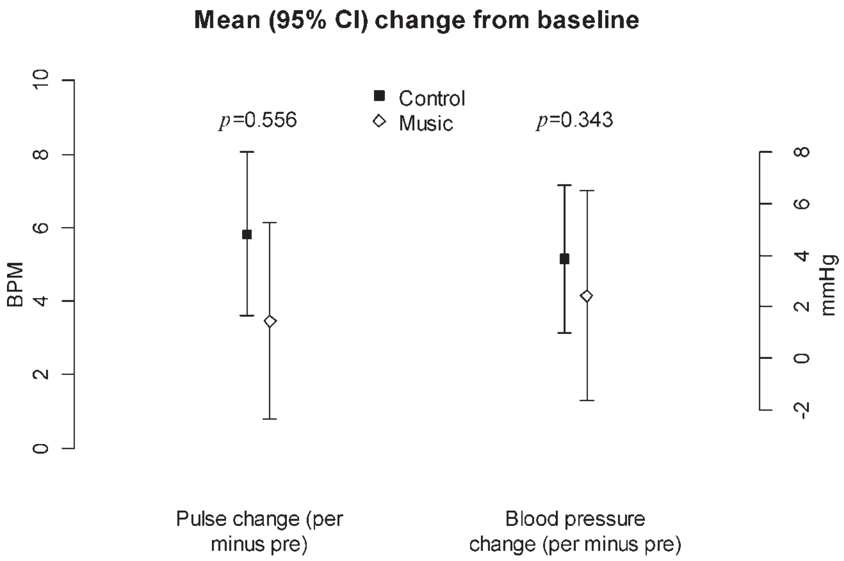

Figure 3. Mean [95% confidence interval (CI)] pre- to per-procedure change in pulse rate [beats per min (BPM)] and blood pressure in the music and control groups. *p*-values are shown for baseline-adjusted tests of difference between groups in pre- to per-procedure change (analysis of covariance).

Conclusion

In conclusion, sedation requirements during IR radiological procedures are significantly reduced by playing patient-selected music. Music acts as an adjunct to patient sedation during IR procedures.

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